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TITLE: "Diverting the Pathway to Substance Misuse by Improving Sleep"

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CONTRACTING ORGANIZATION: HOWARD UNIVERSITY, INC.
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14. ABSTRACT The recent Institute of Medicine report underscores an alarming increase in alcohol and other substance misuse among military personnel. Such problems will likely increase after leaving active duty. Sleep disturbances are very common among Warfighters with recent deployments and are associated with mental health problems and alcohol and other substance misuse. Insomnia is highly intertwined with alcohol and substance use disorders and has been found to motivate continuing and incident misuse. The over-arching premise for this proposal is that targeting sleep disturbance in post-deployed Veterans in a manner that addresses factors that are specific to military service, will reduce and prevent the progression of the common misuse of alcohol and other substances. The goal for this R34 proposal is to develop and test an intervention of which the primary target is disturbed sleep. The intervention will incorporate established sleep behavioral interventions, and include a novel component designed to address nocturnal vigilance, a prominent feature of post deployment sleep interference. We will also assess overall alcohol and drug use in the target population, its relationship with sleep disturbance; include an educational/motivational module addressing substance use and sleep. We will assess the effect of participation on substance use and the degree to which the effect is accounted for by improvements in sleep.									
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1. Introduction

Recent surveys indicate substantial and increasing alcohol and other substance misuse among military personnel. Experience with prior Veteran cohorts suggests that such problems will magnify after leaving active duty service. Recent data also indicate that sleep disturbances are very common among those with recent deployments and that sleep problems are associated with other psychiatric symptoms and misuse of alcohol and other substances. Insomnia is highly intertwined with and has been noted to motivate the onset and continuation of alcohol and substance use disorders. Clinical observation strongly suggests, and emerging data indicate, that the need to maintain vigilance is a critical contributor to post-deployment sleep disturbances. Nocturnal vigilance is not a specific target of established sleep behavioral interventions. The over-arching hypothesis of this proposal is that targeting sleep disturbance in Veterans within a few months or years of deployment in a manner that addresses the nocturnal vigilance that is engendered by military combat, will reduce and prevent the misuse of alcohol and other substances that is common in this population. The goal for this project is to adapt and integrate and then test intervention approaches that target disturbed sleep behaviors, nocturnal vigilance, and the use of substances to induce sleep. The resulting intervention will incorporate established sleep behavioral interventions, and include a novel component for addressing nocturnal vigilance that incorporates recent cognitive behavioral techniques. Alcohol, drug, and prescription medication use will be assessed including its relationship to sleep disturbance. Information regarding established short and longer term effects of substances on sleep will be provided and participants' perceptions of how their use affects their sleep and motivation to modify their use will be assessed. We will assess outcomes related to sleep and alcohol/substance/prescription drug use and the degree to which the effect on the latter is accounted for by improvements in sleep.

The first study phase will serve to fine tune the intervention by enrolling symptomatic participants in its initial prototype. Feedback on the applicability, acceptability, and perceived effectiveness of techniques will be solicited during and following individual treatment episodes. Two initial participant cohorts of 10 will provide further feedback in focus groups. Near the conclusion of the initial study phase the investigators will finalize the intervention protocol influenced by participant preferences and their perceptions of acceptability and effectiveness as well as achievement of acceptable adherence and fidelity. The final treatment protocol will then be compared to a condition that will control for attention and receipt of educational material regarding sleep with evaluation of subjective and objective measurements of sleep, substance use, and quality of life. The proposed study findings will inform larger trials and adaptation of the intervention to varied settings.

2. Keywords

Veterans; deployment; nocturnal vigilance; sleep initiation and maintenance disorders; substance use disorders

3. Accomplishments

- The main goal for this project is to adapt and integrate and then test intervention approaches that target disturbed sleep behaviors, nocturnal vigilance, and the use of substances to induce sleep.
- Goals of the study to be accomplished in the first year are to assemble evaluation tools, finalize initial module descriptions, train interventionists – role play, feedback, recruit participants and enroll them in the intervention development phase

A. Regulatory

- Approval by Georgetown Howard Universities Center for Clinical and Translational Science (GHUCCTS) IRB 2/19/2014
- Submission to USAMRMC/ORP/HRPO 5/29/2014
- Submission to DC VA IRB 6/18/2014
- Receipt of initial response/requests from HARPO 6/27/2014
- Provided additional docs to HARPO, submitted revised IC to GHUCCTS IRB 7/3/2014
- Hired graduate student Mary Katherine Howell as a study interventionist
- Responded to VA IRB scientific reviews 7/23/2014
- Received VA IRB requests for revision, submitted revised docs 8/8/2014
- Received GHUCCTS IRB approval of revised IC 8/15/2014
- Approval by DC VA IRB 8/18/2014
- Approval by USAMRMC/ORP/HRPO 9/09/2014
- Re-reviewed study tools and materials (with in-service discussions in mind), finalized tools 11/1//14
- Revisions to protocol based on recommendations of IPR panel submitted to GHUCCTS IRB, approved 2/2/2015, submitted to HRPO 2/2/2015
- Study staff is applying for privileges so that the study can be run at the VA location.

B. Training

- In-service training on integrating mindfulness techniques into a standard Cognitive Behavioral Therapy paradigm Mary Ann Dutton, PhD 9/11/2014
- In-service training with behavioral sleep intervention expert Wilfred Pigeon, PhD 10/15/2014
- In-service training with motivational interviewing for substance use practitioner Gloria Cain, LCSW 10/21/2014

C. Recruitment

Have now enrolled (consented) 5 participants, 3 have completed the treatment procedure and 1 has completed the 3 month follow up.

- We are intensifying recruitment efforts with repeated contacts, encouraging in-service visits, encouraging word of mouth referrals from participants, and expanding contacts.
- Outreach to several VFW organizations, visit to PG county VFW with further contact planned.

- Outreach to Military Veterans and Society Program of the Center for a New American Security; the DC American Legion; Veterans Program Coordinators for Howard, American, and Georgetown Universities, possible in- services pending. Flyers posted. Meeting with VAMC collaborators pending.

4. Impact

The three participants who have completed the treatment protocol have all been engaged and enthusiastic and endorsed improvement on several of the outcome measures. They have indicated interest in recommending the program to fellow veterans.

5. Changes/ Problems

We have experienced recruitment challenges. To overcome these challenges we have increased our outreach efforts to University Veteran programs, VFWs, & American Legions, and continue to foster liaison activity with VA and military bases. We have also increased our face-to face contact with the surrounding community to promote study awareness.

6. Products

Nothing to report at this time.

7. Participant's & Other Collaborating Organizations

Name:	Dr. Thomas Mellman, MD
Project Role:	Principle Investigator
Nearest person month worked:	8
Contribution to project:	Interacting with participants, overseeing all aspects of study and addressing clinical concerns.

Name:	Dr. Tyish Hall Brown, Ph.D., MHS
Project Role:	Co-Investigator
Nearest person month worked:	8
Contribution to project:	Performing Clinical Interview and assessments on participants

Name:	Ameenat Akeeb, B.S.
Project Role:	Study Coordinator
Nearest person month worked:	8
Contribution to project:	Performing informed consent and data collection

Name:	Mary Katherine Howell, B.A.
Project Role:	Sleep Intervention Facilitator
Nearest person month worked:	8
Contribution to project:	Implementing sleep Intervention strategies with participants

8. Special Reporting Requirements

Nothing to report

9. Appendices

Not applicable